## Message

From: Evdokimov, Evgenij A [Evgenij.Evdokimov@fda.hhs.gov]

**Sent**: 2/8/2016 1:56:13 PM

To: Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]

CC: Dass, Brinda [Brinda.Dass@fda.hhs.gov]
Subject: FW: Oxitec's investigational release protocol

Attachments: Oxitec Field Protocol OX-USA-1 OX513A - 2015 revision V9 without appx - FDA CVM SUBMITTED 28-Dec-2015.pdf;

Review of the field release protocol.docx

From: Evdokimov, Evgenij A

Sent: Tuesday, January 26, 2016 9:29 PM

To: Chris A Wozniak (wozniak.chris@epamail.epa.gov) (wozniak.chris@epamail.epa.gov); Kough, John

(Kough.John@epa.gov); McAllister, Janet C (CDC) (jvm6@cdc.gov)

Cc: Brinda Dass (Brinda.Dass@fda.hhs.gov); Rudenko, Larisa (Larisa.Rudenko@fda.hhs.gov)

**Subject:** Oxitec's investigational release protocol

Dear members of the inter-agency review team,

Attached is the package related to Oxitec's investigational release protocol for the field trial using OX513A mosquitoes in Florida. This package includes two documents- the most current version of Oxitec's investigational release protocol (Version 9) and CVM's review of this protocol. Appendices to the protocol will be distributed in a separate email. We request that you please review both these documents and provide your edits/comments related to substantive issues by COB February 10. In the event you need more time, please let us know as soon as possible. If you have any questions please do not hesitate to contact me 240-402-0712 or email me at <a href="Evgenij.evdokimov@fda.hhs.gov">Evgenij.evdokimov@fda.hhs.gov</a>.

Thank you,

Evgenij

Evgenij Evdokimov, PhD Biologist Animal Biotechnology Interdisciplinary Group, HFV-2 USFDA Center for Veterinary Medicine 7500 Standish Place Rockville, MD 20855

Phone: 240-402-0712 Fax: 240-276-8359

Evgenij.Evdokimov@fda.hhs.gov